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To: NASDAQ OMX Copenhagen Hørsholm, Denmark, 17 November, 2014

Veloxis Announces Publication of Phase III Study of Once Daily Envarsus® XR Demonstrating Non-Inferiority vs. Twice-Daily Tacrolimus in De Novo Kidney Transplant Patients

- *Study published in* American Journal of Transplantation -

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced the publication of the Phase III study (Study 3002) of once-daily Envarsus® XR demonstrating non-inferiority vs. twice-daily tacrolimus (Prograf®) in *de novo* kidney transplant patients in the *American Journal of Transplantation*.

Key points:

- Envarsus® is an extended release formulation of tacrolimus designed for once-daily dosing, flatter pharmacokinetics and greater bioavailability compared to twice-daily tacrolimus or Prograf®.
  - The paper entitled, "Novel Once-Daily Extended-Release Tacrolimus Versus Twice-Daily Tacrolimus in De Novo Kidney Transplants: One-Year Results of Phase III, Double-Blind, Randomized Trial" compared the efficacy and safety of Envarsus to twice-daily tacrolimus (Prograf®).
- The 3002 study was a double-blind, double-dummy study enrolling 543 *de novo* kidney transplant patients. The primary endpoint of the study was a composite endpoint of treatment failure (biopsy-proven acute rejection or BPAR, graft failure, loss to follow up or death) that was evaluated after a 12-month treatment period.
- Envarsus® demonstrated non-inferiority to Prograf® based on the composite endpoint of treatment failure at one year (Envarsus® 18.3%, Prograf® 19.6%)
- Envarsus® showed a similar incidence of adverse events and impact on laboratory results compared to Prograf®
- The mean Envarsus® dose was approximately 15% less than that of the twice-daily tacrolimus dose.
- Envarsus® was approved for marketing in the European Union in July 2014; the U.S. PDUFA data is October 30, 2014.
- Envarsus® XR received Tentative Approval from the U.S. Food and Drug Administration on 31 October.
- The article can be found at: http://onlinelibrary.wiley.com/doi/10.1111/ajt.12955/abstract
- These study results were previously reported by Veloxis on June 27, 2013.

For more information, please contact:

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About Envarsus®
Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus® (tacrolimus prolonged-release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients. In the US, Envarsus®, known as Envarsus® XR (tacrolimus extended-release tablets), has received Tentative Approval as a once-daily tablet version of tacrolimus for prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants. Envarsus® XR has received orphan drug designation in the U.S. Veloxis plans to commercialize Envarsus® XR in the US through its own sales force and in the EU through its partnership with Chiesi Farmaceutici SpA.

About Veloxis Pharmaceuticals
Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis Pharmaceuticals A/S, or Veloxis, is a specialty pharmaceutical company. Veloxis' unique, patented delivery technology, MeltDose®, is designed to enhance the absorption and bioavailability of select orally administered drugs. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit www.veloxis.com.